



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

MAR - 3 2006

Stephen M. Paul, Ph.D.
President
VitaPharmica, Inc.
6 Morgan, Suite 12
Irvine, California 92618

Dear Dr. Paul:

This is in response to your submissions to the Food and Drug Administration (FDA), dated February 14, 2005. Your submissions appear to be intended to be the notifications required by 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)) and 21 CFR 101.93(a).

21 CFR 101.93(a)(3) requires that the notice submitted pursuant to 21 U.S.C. 343(r)(6) and this section be signed by a responsible individual who can certify the accuracy of the information presented and contained in the notice, and that the individual certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading. Your submissions do not meet this requirement in that the notices do not contain the signature of a responsible individual nor does it certify that the firm is in compliance with the requirements of the Act and the regulation. Therefore, your firm has not complied with the notification requirement in 21 U.S.C. 343(r)(6) and must submit notifications in accordance with the requirements in 21 CFR 101.93(a). The failure to submit a valid notice as required by the Act and the agency's regulation may subject the products that are the subject of the notification to regulation under the drug provisions of the Act.

Please contact us if we may be of further assistance.

Sincerely yours,

Linda S. Bellusci Ph.D.
for Susan J. Walker, M.D.
Director

Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

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Page 2 - Dr. Stephen M. Paul

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Los Angeles District Office, Compliance Branch, HFR-PA240



Vita Pharmica

The Best Choice for Your Health™

6 Morgan, Suite 112

Irvine, CA 92618

Phone 1-888-686-3083 • 949-588-8038 • fax 949-588-8086

FEB 23 2005

2/14/2005

CERTIFIED MAIL

Return Receipt Requested

Office of Nutrition Products, Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
FOOD & DRUG ADMINISTRATION
5100 Paint Brush Parkway
College Park, Maryland 20740

To Whom It May Concern:

This letter is submitted pursuant to Section 406 (r)(6) of the Federal Food, Drug, and Cosmetic Act for the purpose of notifying the Agency of statements being made in connection with the marketing of dietary supplements which are being distributed by this company.

The text of the statement that is being made is as follows:

For occasional soreness and stiffness in muscles, ligaments, tendons and joints following exercise or sports activities

The name of the Product is as follows:

MuscleSoothe, 60 Tablets

The dietary ingredients for which this statement is being made are:

San-qi root, dong-quai root, Sichuan teasel rhizome, safflower flower and *Astilbe chinensis* plant.

As required, enclosed are two additional copies of this notification.

The signee certifies that the information contained in this notice is complete and accurate, and that Vitapharmica has substantiation that the statement being made is truthful and not misleading.

Sincerely,

Dr. Stephen M. Paul, PhD
President
Vitapharmica, Inc.

#1022

90951



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6 Morgan, Suite 112

Irvine, CA 92618

Phone 1-888-686-3683 • 949-588-8038 • fax 949-588-8026

FEB 23 2005

January 26, 2005

CERTIFIED MAIL

Return Receipt Requested

Office of Nutrition Products, Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
FOOD & DRUG ADMINISTRATION
5100 Paint Brush Parkway
College Park, Maryland 20740

To Whom It May Concern:

This letter is submitted pursuant to Section 406 (r)(6) of the Federal Food, Drug, and Cosmetic Act for the purpose of notifying the Agency of statements being made in connection with the marketing of dietary supplements which are being distributed by this company.

The text of the statement that is being made is as follows:

Helps Maintain Healthy Lung Function

The name of the Product is as follows:

VentilAid, 90 Capsules

The dietary ingredients for which this statement is being made are:

Rhododendron dahuricum L. leaf extract

As required, enclosed are two additional copies of this notification.

The signee certifies that the information contained in this notice is complete and accurate, and that Vitapharmica has substantiation that the statement being made is truthful and not misleading.

Sincerely,

Dr. Stephen M. Paul, PhD
President
Vitapharmica, Inc.



Vita Pharmica

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6 Morgan, Suite 112

Irvine, CA 92618

Phone 1-888-686-3662 • 949-588-8033 • fax 949-588-8036

FEB 23 2005

February 14, 2005

CERTIFIED MAIL

Return Receipt Requested

Office of Nutrition Products, Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
FOOD & DRUG ADMINISTRATION
5100 Paint Brush Parkway
College Park, Maryland 20740

To Whom It May Concern:

This letter is submitted pursuant to Section 406 (r)(6) of the Federal Food, Drug, and Cosmetic Act for the purpose of notifying the Agency of statements being made in connection with the marketing of dietary supplements which are being distributed by this company.

The text of the statement that is being made is as follows:

BoweLax is a gentle natural herbal for relief of occasional constipation*

The name of the Product is as follows:

BoweLax, 120 Capsules

The dietary ingredients for which this statement is being made are:

bitter orange fruit, magnolia bark, Chinese rhubarb root, dwarf-lily turf root, apricot seed, white peony root, and mirabilatum.

As required, enclosed are two additional copies of this notification.

The signee certifies that the information contained in this notice is complete and accurate, and that Vitapharmica has substantiation that the statement being made is truthful and not misleading.

Sincerely,

Dr. Stephen M. Paul, PhD
President
Vitapharmica, Inc.



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Phone 1-888-686-3683 • 949-588-8038 • fax 949 588-8086

FEB 23 2005

February 14, 2005

CERTIFIED MAIL

Return Receipt Requested

Dr. Robert J. Moore
Branch Chief, Compliance & Enforcement Branch
Office of Nutrition Products, Labeling and Dietary Supplements
FOOD & DRUG ADMINISTRATION (HFS-800)
5100 Paint Brush Parkway
College Park, Maryland 20740

Dear Dr. Moore:

This letter is submitted pursuant to Section 406 (r)(6) of the Federal Food, Drug, and Cosmetic Act for the purpose of notifying the Agency of statements being made in connection with the marketing of dietary supplements which are being distributed by this company.

The text of the statement that is being made is as follows:

Best Essentials promotes advanced cellular nutrition with 40 nutrients

Best Essentials has important nutrients your body needs every day. It contains higher levels of B vitamins, which help convert food into energy and help maintain healthy nervous system function. Plus, it contains antioxidants like lycopene, lutein, grape seed extract, pine bark extract and cranberry extract. **Best Essentials** also contains specific nutrients like Vitamins C, A, and E, Copper, Iron, Zinc, Selenium and Beta carotene to help you maintain a healthy immune system.

The name of the Product is as follows:

Best Essentials, 60 Tablets

The dietary ingredients for which this statement is being made are:

Vitamin A (from vitamin A palmitate and beta-carotene)
Vitamin C (as ascorbic acid and sodium ascorbate)
Vitamin D (as cholecalciferol)
Vitamin E (as dl-alpha tocopheryl acetate)
Vitamin K (as phytonadione)
Thiamin (as thiamin mononitrate)
Riboflavin
Niacin (as niacinamide)
Vitamin B6 (as pyridoxine HCl)
Folate (as folic acid)
Vitamin B12 (as cyanocobalamin)
Biotin
Pantothenic acid (as d-calcium pantothenate)
Calcium (as calcium carbonate and dicalcium phosphate)

Iron (as ferrous fumarate)
Phosphorous (as dicalcium phosphate)
Iodine (as potassium iodide)
Magnesium (as magnesium oxide and magnesium borate)
Zinc (as zinc oxide)
Selenium (as sodium selenate)
Copper (as cupric oxide)
Manganese (as manganese sulfate)
Chromium (as chromium chloride)
Molybdenum (as sodium molybdate)
Potassium (as potassium chloride and potassium iodide)
Boron (as magnesium borate)
Silica (from silicon dioxide)
Vanadium (as sodium metavanadate)
Nickel (as nickelous sulfate)
Tin (as stannous chloride)
Lutein
Lecithin
DHA (Docosahexanoic acid)
Choline (as choline bitartrate)
Inositol
Lycopene
Citrus bioflavonoids
<i>Pinus strobes l.</i> bark extract (Pine bark extract)
<i>Vitis vinifera l.</i> , seed (grape seed extract)
Cranberry fruit extract

As required, enclosed are two additional copies of this notification.

The signee certifies that the information contained in this notice is complete and accurate, and that Vitapharmica has substantiation that the statement being made is truthful and not misleading.

Sincerely,

Dr. Stephen M. Paul, PhD
President
Vitapharmica, Inc.

Enclosures



Vita Pharmica

The Best Choice for Your Health™

6 Morgan, Suite 112

Irvine, CA 92618

Phone 1-888-686-3683 • 949-588-8038 • fax 949-338-5080

January 26, 2005

CERTIFIED MAIL

Return Receipt Requested

Office of Nutrition Products, Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
FOOD & DRUG ADMINISTRATION
5100 Paint Brush Parkway
College Park, Maryland 20740

To Whom It May Concern:

This letter is submitted pursuant to Section 406 (r)(6) of the Federal Food, Drug, and Cosmetic Act for the purpose of notifying the Agency of statements being made in connection with the marketing of dietary supplements which are being distributed by this company.

The text of the statement that is being made is as follows:

Advanced Weight Optimization Formula

The name of the Product is as follows:

FabuLean, 180 Capsules

The dietary ingredients for which this statement is being made are:

Chromium (from chromium amino acid chelate), Vanadyl Sulfate, Magnolia bark (Standardized extract 2% magnolol & honokiol), *Coleus forskohlii* root (Standardized extract 10% forskolin), *Lagerstroemia speciosa* leaf (Standardized extract 1% corosolic acid), *Gynostemma* pentaphyllum leaf (Jioagulan)(Standardized extract 98% *gypenosides*), *Gynostemma* pentaphyllum leaf (Jioagulan)(Standardized extract 98% *gypenosides*), Green tea leaf (Standardized extract 50% polyphenols), Chinese rhubarb root (Standardized 5:1 extract), Chinese ginseng root (Standardized extract 80% ginsenosides), Schisandra fruit (Standardized extract 2% schisandrins), Kudzu flower (Standardized extract 40% isoflavones) and Red-clover leaf and flower (Standardized extract of 2.5% isoflavones)

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Sincerely,

Dr. Stephen M. Paul, PhD
President
Vitapharmica, Inc.